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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,550	02/09/2001	Akihiro Funakoshi	053466/0299	5276

22428 7590 10/07/2005

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EXAMINER

SPECTOR, LORRAINE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,550

Applicant(s)

FUNAKOSHI ET AL.

Examiner

Lorraine Spector, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/22/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 14-26 are pending and under consideration.

The rejection of Claims 14-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants amendments.

The rejection of claims 14, 24 and 25 under 35 U.S.C. 102(b) as being anticipated by Reed et al., Surgical Forum 48:179 is withdrawn in view of applicants amendments.

The rejection of claims 15-23 and 26 under 35 U.S.C. 103(a) as being unpatentable over Reed et al., Surgical Forum 48:179-180, 1997, in view of Sato et al., Cancer Research 53(4):851-6, February 1993, and/or Kishimoto et al., EP 0 791 359 A1 is withdrawn in view of applicants amendments.

Information Disclosure Statement

The information disclosure statement submitted 9/22/2005 has been considered. JP 8-245414 has been lined through, as it is in Japanese, with no English translation provided. However, WO 96/40966 has been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14- 26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al., Cancer Research 53(4):851-6, February 1993, and/or Kishimoto et al., EP 0 791 359 A1, either or both references in view of Gross et al., Hepato-Gastroenterol. 40:522-530, cited by applicants, and Farkas et al., Neuroscience Letters 242(3):147-150. 2/20/98 for reasons of record in the previous Office Action mailed 10/6/2003.

Applicants arguments in the amendment filed 7/29/2005 have been fully considered but are not deemed persuasive. Applicants arguments pertaining to lack of motivation to combine the references are not persuasive for reasons of record. Applicants further argue that there is no reasonable expectation of success. This argument has been fully considered but is not deemed persuasive because as stated in the previous Office Action, it was well known in the art, as evidenced by the primary references, to use anti-IL6-R antibodies to treat IL-6 related conditions. Applicants have provided no fact or evidence to the contrary.

Finally, applicants assert that the Examiner's statement that " the person of ordinary skill in the art would not expect that suppression of the effects of a single cytokine would *completely stop or prevent* (emphasis added) a condition that is due to the effects of multiple cytokines" teaches against a reasonable expectation of success. This argument has been fully considered but is not deemed persuasive because applicants are mis-applying the Examiner's statement. The claims are drawn to treatment, not complete amelioration or absolute prevention. The distinction is crucial. There is no question that the person of ordinary skill in the art would expect at least a reduction in symptoms due to the inhibition of IL-6 activity, as evidenced by the primary references. The issue that it is unpredictable that one could *completely stop or prevent* acute pancreatitis is not germane. Applicants position is further belied by WO 96/40966, provided by applicants, which clearly demonstrates an expectation in the art of success at treating IL-6 associated conditions with anti-IL-6 therapeutics.

Conclusion

No claim is allowed.

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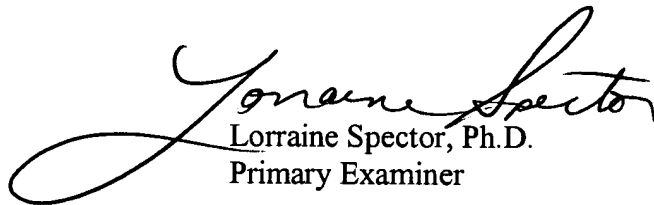
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lorraine Spector, Ph.D.
Primary Examiner